

Notice of Allowability

Application No.

10/081,170

Examiner

S. Devi, Ph.D.

Applicant(s)

KAWAOKA, YOSHIHIRO

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 08/21/06.
2. ☒ The allowed claim(s) ~~is~~ are 1, 3-6, 8-11 and 32-36, now renumbered as claims 1, 2-5, 6-9 and 10-14 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicant's After-final Amendment

- 1) Acknowledgment is made of Applicant's after-final amendment filed 08/21/06 in response to the final Office Action mailed 04/12/06.

Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Janet Embretson in a telephonic interview on 01 September 2006.

I. The title of the specification has been changed as indicated below:

--~~Methods to identify mutant~~ Mutant cells with altered sialic acid.--

II. The specification of the instant application has been amended as indicated below.

(A) The paragraph beginning at line 24 of page 5 of the specification is replaced with the following:

--Figures 1A-1E. Binding of lectin-resistant cell lines. For each cell line, cells were incubated with digoxigenin-labeled *Maackia amurensis* (MAA) lectin or *Sambucus nigra* (SNA) lectin, followed by fluorescein isothiocyanate-labeled antidigoxigenin antibody, and then analyzed by FACS. A) MDCK cells incubated with labeled MAA lectin or labeled SNA lectin; B) MDCK-Ma cells incubated with labeled MAA lectin or labeled SNA lectin; C) MDCK Sn10 cells incubated with labeled MAA lectin or labeled SNA lectin; D) MDCK cells incubated with labeled MAA lectin or labeled SNA lectin; and E) MaKS cells incubated with labeled MAA lectin or labeled SNA lectin. Bold lines, binding of the MAA lectin; narrow lines, binding of the SNA lectin; shaded profiles, negative control (no lectin added).--

(B) The paragraph beginning at line 1 of page 6 of the specification is replaced with the following:

--Figures 2A and 2B. Structures of the NA genes of the AL3(MaKS)-13 and K4(MaKS)-I 3 mutants. (A) The AL3(MaKS)-I 3 contains a 936-nucleotide deletion (from bases 220 to 1253) that removes a large portion of the NA gene coding sequence. This mutation also brings a TAG stop

codon into frame two bases beyond the deletion, so that the gene encodes a 66-amino-acid peptide, corresponding to the cytoplasmic tail, transmembrane region, stalk, and a portion of the head of NA.

(B) The K4(MaKS)-13 NA gene contains a 1,066-nucleotide deletion (from bases 130 to 1193) that removes a large portion of the NA gene coding sequence. This mutation brings a TAG stop codon into frame four bases beyond the deletion, so that the gene encodes a 38-amino-acid peptide, corresponding to the cytoplasmic tail and transmembrane region of the NA gene.--

(C) Claims 12-14 and 16-31 have been canceled.

(D) Claims 1, 6, 8-10, 34 and 36 have been amended as indicated below:

--Claim 1 (Currently amended). An isolated endogenously altered mutant mammalian or avian cell comprising decreased levels of *N*-acetylneuraminic acid and/or decreased levels of *N*-glycolylneuraminic acid relative to a corresponding wild-type cell which wild-type cell supports efficient influenza virus replication, wherein the mutant cell is selected for resistance to growth inhibition by a lectin which binds terminal sialic acid containing residues in sialic acid-containing host cell receptor, wherein the decreased levels of *N*-acetylneuraminic acid and/or the decreased levels of *N*-glycolylneuraminic acid are in the absence of exogenous sialidase not the result of exogenous sialidase treatment.--

--Claim 6 (Currently amended). The isolated mutant cell of claim 5, ~~which~~ wherein the mink cell is a mink lung cell.--

--Claim 8 (Currently amended). The isolated mutant cell of claim 1 which has decreased levels of *N*-acetylneuraminic acid relative to said corresponding wild-type cell.--

--Claim 9 (Currently amended). The isolated mutant cell of claim 1 which has decreased levels of *N*-glycolylneuraminic acid relative to said corresponding wild-type cell.--

--Claim 10 (Currently amended). The isolated mutant cell of claim 1 which has decreased levels of *N*-acetylneuraminic acid and *N*-glycolylneuraminic acid relative to said corresponding wild-type cell.--

--Claim 34 (Currently amended). The isolated mutant cell of claim 1 wherein the lectin specifically binds sialic acid linked to galactose by $\alpha(2-3)$ or $\alpha(2-6)$ ~~linkages~~ linkage.--

--Claim 36 (Currently amended). An isolated endogenously altered mutant mammalian or avian cell ~~which in the absence of exogenous sialidase comprises~~ comprising decreased levels of terminal

sialic acid-containing host cell receptors for influenza virus relative to a corresponding wild-type cell which wild-type cell supports efficient influenza virus replication, wherein the mutant cell is resistant to growth inhibition by *Maackia amurensis* lectin and/or *Sambucus nigra* lectin, wherein the decreased levels of sialic acid-containing host cell receptors are not the result of exogenous sialidase treatment.--

Status of Claims

- 3) Claims 12-14 and 16-31 have been canceled via this Examiner's amendment.
Claims 1, 12 and 36 have been amended via the amendment filed 08/21/06.
Claims 1, 6, 8-10, 34 and 36 have been amended via this Examiner's amendment.
Claims 1, 3-6, 8-11 and 32-36 are pending and are under examination.

Rejection(s) Withdrawn

- 4) The rejection of claims 1, 3-6, 8-11 and 32-35 made in paragraph 9 of the Office Action mailed 04/12/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.
- 5) The rejection of claims 1, 3, 4, 8-10 and 32-36 made in paragraph 11 of the Office Action mailed 04/12/06 under 35 U.S.C. § 102(a) as being anticipated by Takeda *et al.* (*Mol. Biol. Cell.* 11: 3219-3232, September 2000) as evidenced by Ito *et al.* (*J. Virol.* 71: 3357-3362, April 1997, already of record), is withdrawn in light of Applicant's amendment to the base claims.

Remarks

- 6) Claims 1, 3-6, 8-11 and 32-36 are allowed. Claims 3-6, 8-11 and 32-36 have been renumbered as claims 2-5, 6-9 and 10-14 respectively.

The amendments made above to claims 1, 6, 8-10, 34 and 36 have descriptive support in paragraph bridging pages 2 and 3 and pages 3 and 4 of the specification.

- 7) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

- 8) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER